UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ETHICON ENDO-SURGERY, INC. and ETHICON ENDO-SURGERY, LLC, *Plaintiffs and Counterclaim-Defendants*, v. COVIDIEN LP, COVIDIEN SALES LLC, and COVIDIEN AG, *Defendants and Counterclaim-Plaintiffs*.	)	Civil Action No. 1:16-cv-12556-LTS **LEAVE TO FILE UNREDACTED VERSION UNDER SEAL GRANTED ON JUNE 29, 2017 (DKT. NO. 56)**

ETHICON'S MEMORANDUM OF LAW IN OPPOSITION
TO COVIDIEN'S MOTION FOR A PRELIMINARY INJUNCTION

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Ethicon Endo-Surgery, Inc. and Ethicon Endo-Surgery, LLC (together, "Ethicon") submit this memorandum in opposition to Covidien LP, Covidien Sales LLC, and Covidien AG's (together, "Covidien") motion for a preliminary injunction.

INTRODUCTION

Covidien cannot meet its burden to prove that "the drastic and extraordinary remedy" of a preliminary injunction barring Ethicon from manufacturing, using, and/or selling the ENSEAL® X1 Large Jaw device ("ENSEAL X1") is warranted.

[redacted] The alleged novelty of the '284 patent was the use of non-conductive "stop members" in an endoscopic electrosurgical device to create a uniform distance between the upper and lower jaws that grip and seal tissue. [redacted] As an initial matter, ENSEAL X1 is an open surgical device, not approved for use in endoscopic procedures. [redacted] ENSEAL X1 does not have "a ***plurality*** of ***non-conductive*** stop members" that are "configured to maintain a uniform distance between the jaw members," as called for in claim 1 of the '284 patent. Instead, ENSEAL X1 maintains a distance between its jaw members by using a ***single*** pin (not a plurality) made of steel, a ***conductive*** material.

Covidien's contention that Ethicon's steel pin should be considered "non-conductive" is premised on an incorrect claim construction and testing that ignores what actually occurs when the electrically conductive jaw members of ENSEAL X1 are activated during use. Similarly unavailing is Covidien's argument that the polymeric (*i.e.,* plastic) bumps located on the ENSEAL X1's lower jaw member form a "plurality" of stop members that create a uniform distance between the jaw members. As Covidien's expert admits, these bumps are only about

60% the height of the steel pin, which establishes the distance between the two jaw members. Consequently, these bumps do not touch the opposing jaw member in the intended use of the device and do not "maintain a uniform distance between the jaw members" as required.

There are also substantial questions as to the validity of claim 1 of the '284 patent. The Patent Trial and Appeal Board's decision not to initiate an *inter partes* review was premised on a failure to recognize that the prior art reference on which Ethicon was relying actually taught the claim element that the Board thought was lacking. As described below, when this error is corrected, it becomes apparent that using multiple stop members to maintain a uniform gap between opposing jaws of a bipolar electrosurgical device was known in the art at the time of the alleged invention.

Covidien also fails to show irreparable harm. [redacted] Covidien's reliance on alleged loss of reputation, harm to its workforce, and price erosion are speculative and unsupported by evidence. [redacted]

Furthermore, there is no nexus between the alleged inventions of the '284 patent and any competitive advantage that ENSEAL X1 may have over Covidien's existing devices. Ethicon's earlier-released device, which Covidien contends was not commercially successful, has the same mechanism to maintain distance between its jaws as the ENSEAL X1 has—a single, distal pin. ENSEAL X1 is gaining market share because of improvements to its steps of use and ergonomics, not because of the claimed "stop members."

Finally, the balance of the equities and public interest factors weigh against a preliminary injunction. Covidien refused early opportunities to engage in dispute resolution regarding

ENSEAL X1, which would have allowed the parties to seek judicial relief well before ENSEAL X1 was launched; after months of delay, Covidien cannot now credibly claim to need emergency injunctive relief. Additionally, there is a strong public interest in maintaining physician access to devices they prefer for use in surgical procedures.

STATEMENT OF FACTS[1]

I. THE '284 PATENT

The '284 patent issued on August 14, 2012. It shares a common specification and claims priority to an application filed on April 6, 2001. Claim 1, the sole asserted claim in this preliminary proceeding, recites:

> 1. An endoscopic bipolar forceps, comprising:
>
> an elongated shaft having opposing jaw members at a distal end thereof, the jaw members including a length and a periphery and movable relative to one another from a first position wherein the jaw members are disposed in spaced relation relative to one another to a second position wherein the jaw members cooperate to grasp tissue therebetween, the jaw members each including respective flat seal surfaces extending along a respective length thereof and adaptable to connect to a source of electrical energy such that the jaw members are capable of conducting energy through tissue held therebetween to effect a tissue seal;
>
> a plurality of non-conductive stop members disposed along the length of at least one of the seal surfaces of at least one of the jaw members such that the plurality of non-conductive stop members are disposed along the same plane on the seal surface with respect to one another, the non-conductive stop members configured to maintain a uniform distance between the jaw members along the length thereof; and
>
> a knife disposed in operative communication with at least one of the jaw members and translatable to sever tissue disposed between jaw members.

II. THE ENSEAL X1 ELECTROSURGICAL DEVICE

ENSEAL X1, launched by Ethicon in March 2017, is a radio frequency (RF), bipolar electrosurgical device, which is intended for use in open surgeries to cut and seal tissues in order

[1] Ethicon respectfully refers the Court to the attached declarations for a full presentation of the facts. This Statement of Facts contains a brief description by way of background.

to achieve hemostasis (*i.e.*, the process that causes bleeding to stop). *See* Declaration of Karl Leinsing ("Leinsing Decl."), ¶ 16; Dkt. No. 41-8, p. 4 of 8. Bipolar devices, such as ENSEAL X1, seal vessels by grasping tissue between a pair of electrode-tipped jaw members, passing an electrical current through the tissue, varying the power output as needed, and cutting the tissue with a knife blade. Leinsing Decl., ¶ 19.

As shown below, the distal end of the ENSEAL X1 (*i.e.*, the end farthest from the user) comprises a conductive upper jaw seal plate (electrode) and a conductive lower jaw seal plate (electrode). Six black non-conductive bumps protrude through holes in the lower jaw seal plate in order to assist in holding tissue in place. A single conductive, stainless steel pin extends upwardly from the lower jaw member near the distal end of the lower jaw seal plate. This single, distal steel pin sets and maintains the gap between the upper and lower seal plates (electrodes) of the opposing jaw members to prevent them from touching. *Id.*, ¶¶ 27-33, 38-40. The non-conductive bumps do not set or maintain the gap between the opposing jaw members as required by the claims of the '284 patent because they are shorter than the distal steel pin and, consequently, do not touch the upper jaw member. *Id.*, ¶¶ 27-33, 38-40.

[redacted] the bumps are not configured to maintain any distance between the jaw members, let alone a uniform distance. *Id.* ¶ 32; *see also* Declaration of Greg Trees ("Trees Decl."), ¶¶ 6-15.

III. BACKGROUND TO THE PRESENT DISPUTE

Ethicon and Covidien have a long history of patent litigation. Compl., ¶ 30, Dkt. No. 1. Under a 1999 settlement agreement, the parties are required to initially mediate any patent disputes. *Id.*, ¶¶ 31-34. Pursuant to the agreement, in May 2016, in anticipation of the launch of ENSEAL X1, Ethicon served Covidien with a notice of mediation in the hopes of resolving any patent disputes concerning the ENSEAL X1 before its launch. *Id.*, ¶ 42. In response, Covidien refused to engage in mediation, or even to accept samples of the device, despite repeated requests by Ethicon, on the grounds that it was not an approved "product." *Id.*, ¶¶ 43-51. Not until October 2016—five months after Ethicon's notice—did Covidien agree to mediate and to accept samples of the ENSEAL X1. *Id.*, ¶ 52.

On December 19, 2016, the day the mediation concluded, Ethicon filed its complaint for a declaratory judgment of non-infringement of the five patents discussed at the mediation—including the '284 patent. *Id.*, ¶ 1. Covidien sought an extension of its time to answer and waited almost two months to file its response and counterclaims. Covidien's Counterclaims, ¶ 2, Dkt. No. 14. Covidien then waited another two months, until April 25, 2017, to file its motion for a preliminary injunction. Covidien Mem., Dkt. No. 39. The motion was filed more than four months after Ethicon filed its complaint and nearly a year after Ethicon first sought to resolve the dispute through mediation.

ARGUMENT

I. COVIDIEN BEARS A HEAVY BURDEN TO OBTAIN THE EXTRAORDINARY REMEDY OF A PRELIMINARY INJUNCTION

"A preliminary injunction is 'an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.'" *LifeScan Scotland, Ltd. v. Shasta Techs.*, 734 F.3d 1361, 1366 (Fed. Cir. 2013) (quoting *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 22 (2008)); *Nat'l Steel Car v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1324 (Fed. Cir. 2004) (a preliminary injunction is a "drastic and extraordinary" emergency remedy that is "not to be routinely granted"). To obtain the "drastic and extraordinary relief" of a preliminary injunction, a movant must show: (1) likelihood of success on the merits; (2) irreparable harm in the absence of a preliminary injunction; (3) a balance of the hardships in favor of the movant; and (4) that the preliminary injunction favors the public interest. *Murata Mach. USA v. Daifuku Co.*, 830 F.3d 1357, 1363 (Fed. Cir. 2016); *Apple, Inc. v. Samsung Elecs. Co., Ltd.*, 695 F.3d 1370, 1373-74 (Fed. Cir. 2012). All four elements must be satisfied for a court to grant a preliminary injunction. *Winter*, 555 U.S. at 20.

II. COVIDIEN CANNOT PROVE A LIKELIHOOD OF SUCCESS ON THE MERITS

To demonstrate a likelihood of success on the merits, a movant must prove that the non-movant likely infringes the patent and that the claim likely will withstand the non-movant's challenges to the validity of the patent. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). "If the accused infringer 'raises a substantial question concerning either infringement or validity,' then the patentee has not established that it is likely to succeed on the merits, and a preliminary injunction is not appropriate." *LifeScan*, 734 F.3d at 1366.

A. The ENSEAL X1 Does Not Infringe Claim 1

To prove literal infringement, a patentee must show that every limitation found in a

properly construed claim is present in the accused product. *See, e.g., Bowers v. Bayside Techs., Inc.*, 320 F.3d 1317, 1334 (Fed. Cir. 2003).[2] Here, the accused ENSEAL X1 lacks numerous limitations of claim 1 of the '284 patent.

1. The distance between the jaws in the ENSEAL X1 device is maintained by a single steel pin, not by a "plurality" of "non-conductive stop members"

Claim 1 of the '284 patent requires a "plurality of non-conductive stop members" that are "configured to maintain a uniform distance between the jaw members along the length thereof." '284 patent. In order to "maintain a uniform distance between the jaw members," the claimed stop members must ***contact*** the opposing jaw member when the device is closed, essentially acting as physical "stops" or "blocks" that are sandwiched between the two jaw members. Leinsing Decl., ¶ 28. Covidien's technical expert, William Durfee, admitted this, Ginsberg Decl., Ex. 2 (Durfee Tr.), 98:17-99:16, [redacted]

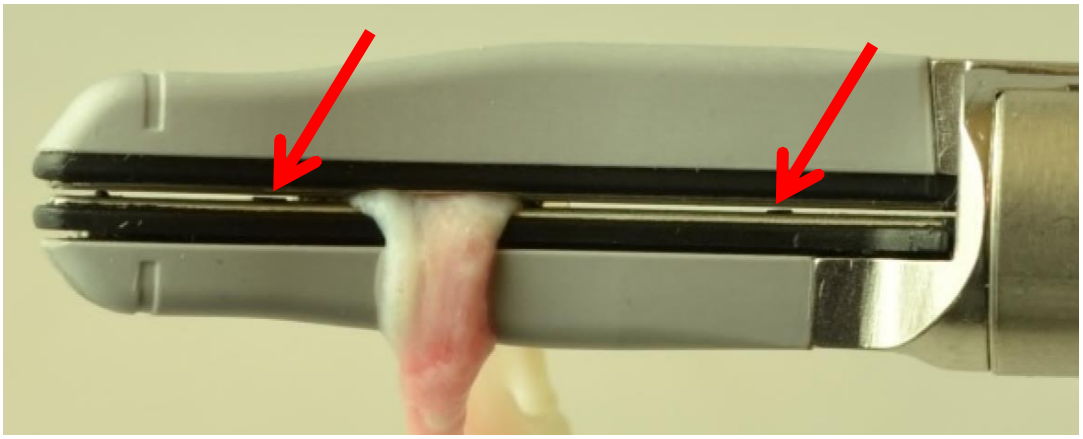
In ENSEAL X1, the only member that contacts the opposing jaw to maintain distance between the jaw members is a single steel pin near the distal tip of the lower jaw member. Trees Decl., ¶ 18; Leinsing Decl., ¶¶ 27-30, 54-55. This pin is configured to contact the upper jaw seal plate and prevent the upper jaw seal plate from touching the lower jaw seal plate. *Id.* Because only the single distal steel pin acts to maintain the gap between the jaws, the ENSEAL X1 device does not meet the claim imitation that requires "***a plurality*** of ***non-conductive*** stop members" that are "configured to maintain a uniform distance between the jaw members."

According to Covidien's expert, six plastic bumps on the lower jaw surface of the

[2] Neither Covidien nor its expert offer any opinions regarding infringement under the doctrine of equivalents. Instead, they assert solely that ENSEAL X1 literally contains each element of claim 1 of the '284 patent. *See, e.g.*, Ginsberg Decl., Ex. 2 (Durfee Tr.), 16:14-17:4.

ENSEAL X1, coupled with the distal steel pin, comprise a "plurality" of non-conductive stop members that set the gap between the jaws. Dkt. No. 41 (Durfee Decl.), ¶¶ 42-44. This is incorrect because the plastic bumps do not touch the upper jaw and therefore do not maintain the distance between the lower and upper jaw members.

Dr. Durfee's own measurements confirm the absence of any contact between the plastic bumps and the upper jaw. Dr. Durfee measured the jaw gap distance between the two seal surfaces of the ENSEAL X1 device to be approximately between 0.007 and 0.008 inches. Dkt. No. 41 (Durfee Decl.), ¶¶ 45-47. But the plastic bumps do not extend that entire distance between the seal surfaces. Rather, there is a gap between the bumps and the upper jaw member of approximately 0.003 inches. Leinsing Decl., ¶ 40. In other words, the bumps cover only approximately 60% of the distance between the opposing seal plates when the jaw members are closed together. *Id.*; *see also* Trees Decl., ¶ 14. This gap is visible in photographs taken by both parties' experts. *See, e.g.*, Dkt. No. 41 (Durfee Decl.), ¶ 34:



See also id., ¶¶ 34, 48; Leinsing Decl., ¶¶ 31, 39-40. [redacted] Trees Decl., ¶ 10; Leinsing Decl., ¶¶ 37-38.

Because they do not contact the upper jaw, the plastic bumps do not maintain the gap distance between the upper jaw member and the lower jaw member. That gap distance is

maintained solely by the steel pin. [redacted]

[redacted]

In his declaration, Dr. Durfee simply ignored the existence of this gap. Indeed, he acknowledged that in the infringement analysis he provided, the gap between the jaw members is dictated "***entirely***" by the single steel pin. *See* Ginsberg Decl., Ex. 2 (Durfee Tr.), 94:7-21

(emphasis added); 119:11-121:7, 183:21-185:2; *see also* Dkt. No. 41 (Durfee Decl.), ¶¶ 45-48. When pressed on the issue in his deposition, Dr. Durfee unveiled a new theory not previously disclosed in his declaration. He testified that he was able to cause the polymeric bumps to touch the opposing jaw seal surface by applying an external force to the instrument, that is, by "squeezing down in the middle of the jaws" of the device with his "[f]ingers." Ginsberg Decl., Ex. 2. (Durfee Tr.), 64:25-66:22.

Dr. Durfee's undisclosed "squeezing" theory should be rejected for multiple reasons. First, there is no evidence that his squeezing test bears any relationship to the conditions under which the ENSEAL X1 device is used. Dr. Durfee testified that he had never seen or heard of a real-life situation where the polymeric bumps of an ENSEAL X1 device actually touched the sealing surface on an upper jaw member. Ginsberg Decl., Ex. 2 (Durfee Tr.), 195:21-197:19. [redacted] In reality, the amount of compressive force required to squeeze the jaw members together so that the polymeric bumps touch the upper seal surface is substantially greater than the forces that the device encounters during normal operation to cut and seal tissue. Leinsing Decl., ¶ 43. Indeed, it would be a misuse of the device to squeeze the jaws together in the manner suggested by Dr. Durfee. *Id*.

Even if Dr. Durfee's finger squeeze test were relevant, which it is not, the polymeric bumps would still not meet the claim limitations because they would not maintain a "***uniform***" distance between the jaw members. As the intrinsic record makes clear, the claimed "uniform distance between the jaw members along the length thereof" means that the distance between the jaw members is the ***same*** along the entire length of the jaws. Leinsing Decl., ¶ 44. But when the middle of the jaw members is squeezed, the distance between the jaws is not the same along the length; it is less in the middle, where the jaws are being compressed, than at the end, where the

distal pin is disposed. In short, Dr. Durfee's infringement theory fails. Leinsing Decl., ¶¶ 45-51.

2. The steel pin that maintains the distance between the jaws in the ENSEAL X1 is conductive, not "non-conductive"

ENSEAL X1 also does not infringe claim 1 of the '284 patent because its gap-setting, distal pin is made of stainless steel, a material that is indisputably conductive. Trees Decl., ¶ 17. The term "non-conductive stop member" would be understood by a person of skill in the art to mean a stop member comprised of a material that is non-conductive, *i.e.*, that is not capable of conducting electricity. Leinsing Decl., ¶¶ 56, 66. This construction is supported by the intrinsic record. Indeed, the only materials that the '284 patent specification discloses for the stop members do not conduct electricity. Ginsberg Decl., Ex. 4 ('284 patent), 4:30-42.

There is no dispute that the distal steel pin conducts electricity. Both parties' experts confirmed this by using a multimeter to measure the resistance between the ENSEAL X1's distal steel pin and the upper jaw seal plate. Leinsing Decl., ¶¶ 59-64; Ginsberg Decl., Ex. 2 (Durfee Tr.), 177:21-180:16. Thus, the ENSEAL X1 does not have the limitation of "a plurality of ***non-conductive*** stop members" to maintain a uniform distance between the upper and lower jaws.

In his declaration, Dr. Durfee opines that the distal steel pin nonetheless should be considered "non-conductive" because it is separated from the lower jaw by a non-conductive layer. Dkt. No. 41 (Durfee Decl.), ¶¶ 42-44. There are two problems with this theory. First, a person of ordinary skill in the art would understand that the term "non-conductive" refers to the material used to make the stop member. Leinsing Decl., ¶ 56. Second, even assuming, incorrectly, and in theory, that a conductive stop member could become "non-conductive" because of the way it is mounted, the distal steel pin on the ENSEAL X1 at issue here is conductive because it conducts electricity while the device is in use. During surgery, tissue often comes into contact with the pin and the lower jaw seal plate, creating a direct electrical linkage

between them. Trees Decl., ¶ 20; Leinsing Decl., ¶ 60. Since the electric current powering the device is alternating current (AC), electricity flows back and forth through the tissue between the distal steel pin (return path) and the lower jaw seal plate (active path). *Id.* Dr. Durfee repeatedly conceded this point in his deposition. Ginsberg Decl., Ex. 2 (Durfee Tr.), 45:11-46:5, 48:16-49:14, 135:16-135:24, 138:16-140:8. [redacted]

Confronted with the fact that the ENSEAL X1's distal steel pin conducts electricity, Dr. Durfee testified in his deposition that he still considered it "non-conductive" because it would not cause the device to short-circuit in use. Ginsberg Decl., Ex. 2 (Durfee Tr.), 48:17-50:8, 52:19-53:6. But this theory, which does not appear in Dr. Durfee's declaration, rests on an unreasonable construction that would define stop member as non-conductive even if it conducts electricity, as long as it does not short-circuit the system in which it operates. This is not how a person of ordinary skill in the art would interpret the term "non-conductive stop member" in claim 1 of the '284 patent. Leinsing Decl., ¶ 65. Instead, this term is properly construed to mean a stop member made of a material that is not capable of conducting electricity. *Id.* A stop member can be conductive even if it does not cause a short-circuit. Because the distal steel pin of the ENSEAL X1 conducts electricity, it is not a "non-conductive stop member."[3]

[3] The ENSEAL X1 distal pin does not cause the device to short-circuit when the jaw members are closed during use because the pin has the same electrical potential as the upper jaw seal plate (electrode). *Id*., ¶ 59. [redacted]

3. The ENSEAL X1 does not have a "plurality" of stop members "disposed along the length of a least one of the seal surfaces the jaw members" and "disposed along the same plane"

In addition, the ENSEAL X1 device does not meet the claim limitation requiring that the "stop members are disposed along the same plane on the seal surface with respect to one another." As discussed above, when the jaws of the ENSEAL X1 are in the closed position, the polymeric (*i.e.*, plastic) bumps are approximately 0.003 inches from the upper jaw. *See supra* at pp. 7-8. The distal steel pin, however, extends higher than the polymeric bumps and is in contact with the upper jaw seal plate. Thus, the distal steel pin and the polymeric bumps are not "disposed along the same plane on the seal surface with respect to one another," and fail to satisfy this additional limitation of claim 1 of the '284 patent.

In his deposition (but not in his declaration), Dr. Durfee testified that the "same plane" limitation in claim 1 "has to do with the bottom part of the stop members where they start and it doesn't say anything about the height of the stop members." Ginsberg Decl., Ex. 2 (Durfee Tr.), 87:18-88:6. As Ethicon's expert Dr. Leinsing explains, that is an incorrect construction of the term because the claim focuses on providing a uniform gap between the jaw members, which turns on the height of each of the stop members. Leinsing Decl., ¶ 73. However, as shown in the figure below, even if the Court were to accept Dr. Durfee's claim construction, his conclusion that the ENSEAL X1 device meets this limitation would still be incorrect. The polymeric bumps are mounted on the lower seal surface (electrode), while the distal steel pin begins from a point well below the point at which the polymeric bumps begins:

Leinsing Decl., ¶ 71; *see also id.*, ¶ 27. Even if the relevant "plane" were defined by the bottom of the stop members, the distal pin and the polymeric bumps would not be on the "same plane." Further, since the steel pin is spaced apart from the seal surface, unlike the non-conductive bumps, which contact the seal surface, the steel pin does not satisfy the requirement that the "stop members" be disposed along the length of one of the seal surfaces." *Id.* Dr. Durfee appears to have overlooked these facts and his theory, therefore, fails.

4. The ENSEAL X1 device is not an endoscopic forceps

The preamble of all of the claims of the '284 patent, including claim 1, calls for an "endoscopic bipolar forceps." The claimed invention is consistently and repeatedly referred to

throughout the specification as being directed to an endoscopic bipolar forceps including in the abstract, the summary of the invention, the description of the drawings, and the detailed description of the invention, including every described embodiment. Although the preamble of a patent claim is sometimes treated as non-limiting in nature, the repeated use of a term throughout the specification to describe the invention weighs in favor of the term being construed as a claim limitation. *See Poly-America, L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1310 (Fed. Cir. 2004); *Karsten Mfg. Corp. v. Cleveland Golf Co. Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1379 (Fed. Cir. 2001). *See also Rotatable Techs. LLC v. Motorola Mobility LLC*, 567 Fed. Appx. 941, 943 (Fed. Cir. 2014). Here, in light of the repeated and consistent use of "an endoscopic bipolar forceps" to describe the invention in the '284 patent, the preamble term should be considered limiting.

The ENSEAL X1 is not an endoscopic device. Rather, its approved indicated uses are limited to open surgical procedures. *See, e.g.*, Ginsberg Decl., Ex. 5 (FDA 510(k) pre-market approval notice for the ENSEAL X1 device, dated September 9, 2016, including indications for use), p. 4 of 8. Ethicon promotes ENSEAL X1 exclusively for use in open surgical procedures. *See, e.g.*, Dkt. Nos. 40-5 and 40-6. It does not promote the device for endoscopic procedures (which involve inserting a small tube-like instrument into a patient's body through an incision). Dr. Durfee acknowledged that endoscopic procedures are not open surgical procedures. Ginsberg Decl., Ex. 2 (Durfee Tr.), 34:2-22. Accordingly, the ENSEAL X1 device does not meet the preamble limitation of an "endoscopic bipolar forceps."

5. Covidien failed to perform any claim construction analysis

Covidien's infringement contentions are premised on a number of implicit claim constructions that it fails to justify. The first step in determining whether a patent is infringed is to construe the claim language as a matter of law. *See Nazomi Communs. v. Nokia Corp.*, 739

F.3d 1339, 1343 (Fed. Cir. 2014). Where, as here, the parties have a "fundamental dispute" as to the scope of claim, courts are required to conduct a claim construction analysis. *O2 Micro Intern. Ltd. v. Beyond Innov. Tech. Co*., 521 F. 3d 1351, 1362 (Fed. Cir. 2008).

There is no exception to this requirement on a motion for a preliminary injunction. *See Shuffle Master, Inc. v. VendingData Corp.*, 163 F. App'x 864, 868 (Fed. Cir. 2005) (noting that if a preliminary injunction "turns on a contested issue of claim construction, the court must give the claim construction issue the attention necessary to determine the likelihood of success"). Indeed, a movant's failure to address claim construction in its opening brief may, by itself, result in the patentee failing to prove a likelihood of success on the merits. *See Millipore Corp. v. W.L. Gore & Assocs.*, No. 11-1453, 2011 U.S. Dist. LEXIS 130206, at *19-32 (D.N.J. Nov. 9, 2011) (movant who did not offer a proposed construction failed to carry its burden of showing likelihood of success on the merits); *Fair Isaac Corp. v. IBM*, No. 05-2081, 2006 U.S. Dist. LEXIS 27778, at *15-18 (D. Minn. May 9, 2006) (same).

Here, Covidien failed to mention, let alone analyze, claim construction in its opening brief. Covidien's expert attempts to dodge this issue by contending that he was not engaging in claim construction, but was simply adopting "a plain and ordinary meaning" for all of the claim terms at issue. *See* Dkt. No. 41 (Durfee Decl.), ¶ 18; Ginsberg Decl., Ex. 2 (Durfee Tr.), 50:10-17, 152:24-153:4.

Yet, as the above discussion makes clear, Dr. Durfee's infringement analysis relies on anything but the "plain and ordinary meaning" of the claim terms. For example, Dr. Durfee's "squeezing" test, discussed above, apparently wrongly assumes that the distance between the jaw members can be "uniform" even when middle of the jaw members is bowed by an external force. *See* Leinsing Decl., ¶¶ 43-51. That certainly does not conform to any "plain and ordinary

meaning" of the term "uniform." Dr. Durfee's analysis of the "non-conductive" limitation wrongly assumes that the term has the additional requirement of avoiding short-circuits rather than simply the capacity to conduct electricity. *See* Leinsing Decl., ¶ 65. And Dr. Durfee's analysis of the "same plane" limitation is premised on the incorrect assumption that the claim is referring to the bottom parts of the stop members rather than their heights. *See* Leinsing Decl., ¶ 73. As noted, Ethicon disagrees with each of these proposed constructions. For the reasons discussed above, Covidien's implicit claim constructions should be rejected out of hand. But, in any event, Covidien's motion should be denied for failure to conduct the requisite claim construction analyses. *See Millipore Corp.*, 2011 U.S. Dist. LEXIS at *19-32.

B. There Is A Substantial Question As To The Validity Of Claim 1 of The '284 Patent

The Federal Circuit has summarized the standard for assessing the validity of a patent in the context of a preliminary injunction motion as follows:

> Validity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial…. In resisting a preliminary injunction, [] one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself.

Amazon.com, 239 F.3d at 1358-59. Covidien's primary argument regarding validity is that the Patent Trial and Appeal Board ("PTAB") declined to initiate *inter partes* review proceedings regarding claim 1 of the '284 patent. Dkt. No. 39 (Covidien Mem.) at 18. As set forth below, the PTAB's prior decisions overlooked key aspects of the prior art and should have no impact on the validity issues before this Court. Indeed, substantial evidence shows that claim 1 of the '284 patent is vulnerable to a validity challenge.

1. Claim 1 of the '284 patent is obvious over the prior art

Under 35 U.S.C. § 103, a patent is invalid as obvious when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." Obviousness is a question of law based on underlying factual inquiries including (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art, and (4) secondary considerations of non-obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

The use of a plurality of non-conductive stop members to set a uniform gap between jaw members in an endoscopic bipolar surgical device, the sole alleged differentiating feature from the prior art, was known in the art prior to April 6, 2001, the earliest possible priority date of the '284 patent. Leinsing Decl., ¶¶ 78, 86-88, 90-101.

For example, U.S. Patent No. 5,674,220 to Fox et al. ("Fox"), which issued on October 7, 1997, discloses "a bipolar endoscopic clamping, coagulation and cutting device" with a pair of opposing jaw members. *Id.*, Ex. 8; ¶¶ 83, 104. Fox discloses a pair of jaw members each including respective flat tissue grasping surfaces (electrodes) extending along a respective length thereof and adaptable to connect to a source of energy such that the jaw members are capable of conducting energy through tissue held therebetween to effect a tissue seal. *Id.*, ¶ 87. Fox teaches including an "island of insulation" on one of the grasping surfaces to establish an insulative gap between the conductive seal surfaces to prevent short-circuiting. *Id.*, ¶ 86. Fox also discloses disposing tissue grasping teeth on each of the tissue grasping surfaces to assist in holding the tissue disposed therebetween. *Id.*, ¶ 88. Fox further discloses a knife disposed in operative communication with both jaw members and translatable to sever the tissue. *Id.*, ¶ 118.

Similarly, U.S. Patent No. 5,891,142 to Eggers et al. ("Eggers"), which issued on April 6, 1999, discloses "an improved surgical forceps . . . which achieve a highly efficient hemostasis of gripped tissue or vessels." *Id.*, Ex. 9; ¶ 90. Eggers discloses a device dimensioned for use in endoscopic procedures with oppositely-disposed tip regions (*i.e.*, jaw members) that are movable such that they can grasp tissue. *Id*., ¶¶ 105-106. These tip regions have "flat, electrically conductive tissue grasping surfaces" for "sealing or congealing of tissue or vessels" using RF energy. *Id.*, ¶ 106. Eggers further teaches including a plurality of insulative spacers (*i.e.*, stop members) having a uniform thickness disposed along the length of the tissue gasping surface. *Id.*, ¶ 90-92. Such spacers originate and terminate from the same point on the grasping surface to set a uniform gap between the jaw members, thereby preventing the grasping surfaces from contacting one another and short-circuiting, and to assist in grasping tissue. *Id.*

A person of ordinary skill in the art would have been motivated to combine the teachings of Fox and Eggers to arrive at the invention disclosed in claim 1 of the '284 patent, rendering the same invalid for obviousness. *Id.*, ¶¶ 120-125. Fox teaches the use of tissue grasping teeth that protrude from the flat seal surfaces (electrodes) on the opposing jaw members of an endoscopic forceps, such that they create a biting surface. *Id.*, ¶ 88.

A skilled artisan would have recognized that Eggers teaches the advantages of using insulative spacers on at least one of the seal surfaces of a bipolar electrosurgical device to avoid short-circuiting and to assist in the gripping of tissue in order to achieve an effective seal. *Id.*, ¶¶ 95-101. Specifically, Eggers teaches that when tissue is grasped, the "extrusion of the tissue or vessel media into the recesses between the [insulative spacers] serves to achieve a secure grasping thereof during its surgical manipulation and throughout the coagulation process." *Id.*, ¶ 97. Eggers notes that highly polished electrodes are often poor at grasping, while serrated

grasping surfaces (like those disclosed in Fox) can be difficult to clean since they "tend to trap debris and coagulum." *Id.*, ¶¶ 98-100, 120. As a solution that avoids the known problems with prior art devices, Eggers teaches that inclusion of insulative spacers results in the proper balance between high tissue grasping capability and cleanability of the tissue grasping surfaces. *Id.*

A person of ordinary skill in the art would have been motivated to modify the electrosurgical device of Fox by replacing the tissue grasping teeth with the insulative spacers taught in Eggers to provide the proper balance between high tissue grasping capability and cleanability of the tissue grasping surfaces. *Id*., ¶ 120. The resulting bipolar endoscopic device would include all of the elements of claim 1 of the '284 patent, namely: a pair of opposing jaws movable relative to one another; the jaw members each including a flat seal surface extending along a respective length thereof and capable of conducting energy through tissue held therebetween to effect a tissue seal; a plurality of non-conductive stop members (insulative spacers) disposed along the length and same plane of one of the seal surfaces to maintain a uniform distance between the jaw members along the length thereof; and a knife in operative communication with one of the jaw members. *Id.*, ¶ 124. Therefore, the subject matter of claim 1 of the '284 patent would have been obvious to a person of ordinary skill in the art at the time of the alleged invention. For the Court's convenience, an exemplary invalidity claim chart is provided. *See* Leinsing Decl., Ex. 2.

2. Covidien's validity arguments are unsound

Covidien's primary argument is that the PTAB has twice declined to initiate IPR proceedings regarding claim 1 of the '284 patent. Dkt. No. 39 (Covidien Mem.) at 18. The PTAB's decisions, however, have no bearing on the validity question now before this Court.

The PTAB's decision not to institute a trial in IPR2015-01275 rested on a failure to recognize one teaching of Eggers and a failure to properly interpret another. According to the

PTAB, Ethicon "did not point to sufficient evidence or present argument to show that" the prior art teaches "a uniform distance between the jaw members along the length thereof." Leinsing Decl., ¶ 80. Though neither Ethicon nor Covidien identified this latter phrase as a term requiring construction, the PTAB identified it on its own and construed it to require a uniform distance "when the tissue is held between the opposing jaw members." *Id.* The PTAB held that because the figure from Eggers that Ethicon cited in its petition (Fig. 11) "represents the distance between two grasping surfaces *without any tissue*," Ethicon failed to show that Eggers teaches this element as construed by the PTAB. *Id.* (emphasis added). The PTAB, however, overlooked that Fig. 26 of Eggers shows a uniform distance between the jaw members along the length thereof when tissue is disposed between the opposing jaw members. *Id*., ¶¶ 80, 94. Had the PTAB noticed and correctly interpreted the teaching of Fig. 26, it would have realized that Fig. 26 cures the stated deficiency with respect to Fig. 11. *Id.*, ¶ 112.

In denying institution in IPR2015-01275, the PTAB also noted that in Eggers, "the tines are bowed," and as a result, "the distance between the tines (or the grasping surfaces) is not uniform along the length thereof." Leinsing Decl., ¶ 111. While the PTAB noted that the distance between the tines may not be uniform as a result of the bowing, it failed to recognize that the distance between the electrically operative tip regions (*i.e.*, the jaw members) is uniform along the length thereof. This is because the bowing is affected in the tines, which are the prongs of the Eggers forceps that extend up to, but ***outside*** of the tip regions. *Id.* Further, even if the tip regions are bowed themselves—and they are not—the curvatures would be smoothed out when all of the insulative spacers come into contact "[u]pon further pressure." *Id.*

The second IPR petition, IPR2016-00944, was denied on purely procedural grounds. Although Ethicon directed the PTAB to Fig. 26 of Eggers, the PTAB did not address that

teaching. Instead, the PTAB denied institution of the IPR on the ground that Ethicon had already filed one IPR petition on the '284 patent. *Id.*, ¶¶ 112, n.4.

On the current record, the validity of claim 1 of the '284 patent is unquestionably "vulnerab[le]," and a preliminary injunction should not issue. *Amazon.com*, 239 F.3d at 1359-60.

III. COVIDIEN CANNOT ESTABLISH IRREPARABLE HARM

Covidien cannot establish irreparable harm because any lost sales and profits attributable to the ENSEAL X1 are easily quantifiable. *See eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006); *Eli Lilly & Co. v. American Cyanamid Co.*, 82 F.3d 1568, 1578-79 (Fed. Cir. 1996).

Because the relevant market is characterized by relatively few sellers and large-volume buyers such as hospitals, any potential economic damages to Covidien resulting from the alleged infringement could be determined with reasonable precision. Declaration of Ryan Sullivan, Ph.D. ("Sullivan Decl."), ¶¶ 45-51. [redacted]

[redacted]

Covidien's arguments as to other types of alleged harm lack any support. *See* Sullivan Decl., ¶¶ 69-76. First, Covidien argues that it is experiencing reputational harm because the ENSEAL X1 is supposedly causing the market to "incorrectly see[] Ethicon, rather than patentee Covidien," as an innovator. Dkt. No. 39 (Covidien Mem.) at 22; Dkt. No. 40 (Chindlund Decl.), ¶¶ 34-37. [redacted]

Covidien's price erosion allegations are equally baseless. Dkt. No. 40 (Chindlund Decl.),

¶ 38. [redacted]

Finally, Covidien offers no proof of its assertion that sales of ENSEAL X1 jeopardizes its employees' jobs. Dkt. No. 39 (Covidien Mem.) at 23; Dkt. No. 40 (Chindlund Decl.), ¶ 49. [redacted]

IV. THERE IS NO NEXUS BETWEEN THE ALLEGED INFRINGEMENT AND THE CLAIMED HARM

To secure injunctive relief, Covidien must "show that the infringing feature drives consumer demand for the accused product." *Apple*, 695 F.3d at 1375. Covidien argues that consumer demand for ENSEAL X1 is driven by its ability to create a consistent and reliable seal, and that this is the result of the uniform distance between the two sealing surfaces. Dkt. No. 39 (Covidien Mem.) at 23-24. This argument fails for several reasons. *See* Sullivan Decl., ¶¶ 52-64.

To support its nexus argument, Covidien contrasts the ENSEAL X1 with Ethicon's earlier device, the ENSEAL G2 Super Jaw. Covidien contends that the ENSEAL G2 Super Jaw "has not

been able to gain substantial market share due to the Enseal line's poor performance as a vessel sealer," Dkt. No. 40 (Chindlund Decl.), ¶22, and that this allegedly poor performance was because ENSEAL G2 Super Jaw "did not utilize stop members on the lower jaw sealing surface." Dkt. No. 39 (Covidien Mem.) at 24. According to Covidien, the ENSEAL X1 uses the patented invention to overcome the purported sealing deficiencies of the ENSEAL G2 Super Jaw.

But this argument is contrary to the record. [redacted] And there certainly is no evidence that the vessel sealing capabilities of the ENSEAL X1 are related to the "non-conductive bumps" claimed by the '284 patent. [redacted]

Furthermore, the ENSEAL X1 and the ENSEAL G2 Super Jaw maintain a gap between their jaws in the same way. The gap distance between the seal surfaces on the ENSEAL X1, as described above, is maintained by a single distal steel pin. The ENSEAL G2 Super Jaw uses ***the same mechanism*** to maintain the gap distance: a single distal steel pin. Leinsing Decl. at ¶¶ 131-132; Trees Decl., ¶ 21. [redacted]

[redacted]

Accordingly, some other factor or factors must drive consumer demand for ENSEAL X1. One major factor that distinguishes ENSEAL G2 Super Jaw from ENSEAL X1 is the steps of use of the products. With ENSEAL G2 Super Jaw, the sealing and cutting functions occur simultaneously, whereas with ENSEAL X1, the sealing function occurs first, and the cutting function occurs next. Trees Decl., ¶ 22. Many surgeons prefer the sealing and cutting functions to occur in separate steps, as in the ENSEAL X1 device. *Id.*; *see also* Sanzone Decl., ¶¶ 18, 20. Ethicon has featured separate seal and cut functionality prominently in its promotional materials for ENSEAL X1. *See, e.g.*, Ginsberg Decl., Ex. 14 (EESENS_00033859). Other key factors driving demand for ENSEAL X1 include its improved ergonomic design, as well as economic factors such as price and Ethicon's relationships with some facilities. Sullivan Decl., ¶¶ 58-60, 62-64. None of these factors has anything to do with the supposed novelty of the '284 patent.

[redacted] *See Marine Travelift, Inc. v. ASCOM SpA*, No. 14-443, 2014 U.S. Dist. LEXIS 118202, at *43 (E.D. Wisc. Aug. 25, 2014) (no nexus where patentee "never even *mentioned*, much less touted, its invention's supposedly important benefits") (emphasis in original). [redacted]

V. THE BALANCE OF EQUITIES WEIGHS IN ETHICON'S FAVOR

The balance of equities factor requires the Court to "balance the harm that will occur to the moving party from the denial of the preliminary injunction with the harm that the non-moving party will incur if the injunction is granted." *Hybridtech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1457 (Fed. Cir. 1988). An injunction should not issue "if its impact on the enjoined party would be more severe than the alleged injury the moving party would suffer if it is not granted." *See, e.g., Litton Sys., Inc. v. Sunstrand Corp.*, 750 F.2d 952, 959 (Fed. Cir. 1984). The equities here strongly favor Ethicon. *See* Sullivan Decl., ¶¶ 84-95.

Covidien's months-long refusal to engage in early dispute resolution efforts before filing the present motion undercuts its demand for emergency relief. *See supra* Statement of Facts, Section III. Courts hold a party's delay in seeking relief against it when analyzing whether that party is entitled to a preliminary injunction. *See, e.g., Apple Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1325-26 (Fed. Cir. 2012) (upholding denial of a preliminary injunction and noting that "the [district] court looked to Apple's overall diligence in seeking a preliminary injunction, and concluded that, on balance, Apple's delay in diligently pursuing its infringement claim against Samsung tips in Samsung's favor"); *Hybridtech, Inc.*, 849 F.2d at 1457; *Tennant Co. v. Hako Minuteman, Inc.*, 651 F. Supp. 945, 961 (N.D. Ill. 1986).

Had Covidien accepted Ethicon's initial request to mediate and moved expeditiously after the mediation to institute litigation, proceedings in this action would be nearly a year ahead of where they are. Whatever Covidien's reasons for refusing Ethicon's early efforts at mediation, its actions were not those of a company in a hurry. In light of this record, Covidien should not be rewarded with the drastic and extraordinary remedy of a preliminary injunction. *See Max-Planck-Gesellschaft zur Forderung der Wissenschaften E.V. v. Whitehead Inst. for Biomedical Research*, 650 F. Supp. 2d 114, 123 (D. Mass. 2009) ("A party cannot delay the initiation of

litigation and then use an 'emergency' created by its own decisions concerning timing to support a motion for a preliminary injunction.").

Meanwhile, Ethicon would experience significant harm if an injunction were to issue, even if that injunction were later overturned. Launching a new device, such as the ENSEAL X1, requires building momentum for the product by training a sales organization, building awareness in the market with clinical and economic stakeholders, and managing a supply chain. Sanzone Decl., ¶ 6. If an injunction were to issue, all of these efforts would be disrupted and set back in ways that would be hard to measure. *Id.*, ¶¶ 7-12. This is not speculative; it is exactly what happened in 2014, when Covidien obtained a brief preliminary injunction against a different Ethicon device and the injunction was quickly dissolved on appeal because Covidien's patents were held invalid. *Id.*, ¶¶ 13-15.

In support of its argument that the balance of equities weighs in its favor, Covidien relies on two ***permanent*** injunction cases, *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142 (Fed. Cir. 2011) and *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995 (Fed. Cir.1986). In those cases, the calculus was different, because validity and infringement had already been adjudicated at trial, whereas here, Covidien has not demonstrated a likelihood of success on the merits. *See, e.g., Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 546 n.12 (1987) (noting that a permanent injunction requires "actual success" on the merits while a preliminary injunction requires only "a likelihood of success").[4] In light of Covidien's delay in resolving this dispute and the fact that Ethicon is in the midst of its crucial launch activities, the equities weigh against

[4] Covidien's reliance on *Sanofi-Synthelabo v. Apotex, Inc*., 488 F. Supp. 2d 317, 345 (S.D.N.Y. 2006) fares no better. That case involved a defendant who specifically elected under the Hatch-Waxman Act to launch its product at risk before the conclusion of litigation. *Id*. at 345-46. Here, as noted above, Ethicon made every effort to resolve this matter early. Furthermore, the impact of a competitive surgical device is not comparable to the impact of a generic drug of an innovator drug, in which almost all of the sales of the innovator drug are replaced in short order.

granting a preliminary injunction.

VI. THE PUBLIC INTEREST IS BEST SERVED BY KEEPING THE ENSEAL X1 AVAILABLE TO PHYSICIANS

The public interest is best served by allowing the ENSEAL X1 to remain on the market because the device is highly valued by the surgeons who are using it. *See Hybridtech, Inc.*, 849 F.2d at 1458 (Fed. Cir. 1988) (affirming denial of a preliminary injunction for two classes of medical products where the products were needed by the public, despite findings of irreparable harm and likelihood of success on validity and infringement); Sullivan Decl., ¶¶ 77-83.

A number of surgeons prefer to use the ENSEAL X1, and have already experienced great success with the device, achieving very positive outcomes for their patients. [redacted]

It would be inconsistent with public interest to require surgeons who wish to use ENSEAL X1 to cease using it. *See Datascope Corp. v. Kontron, Inc.*, 786 F.2d 398, 401 (Fed.

Cir. 1986) (affirming denial of a preliminary injunction against sales of a medical device that "some physicians prefer"); *Cordis Corp. v. Boston Scientific Corp.*, 99 F. App'x 928, 935 (Fed. Cir. 2004) (affirming denial of a preliminary injunction in reliance on the "strong public interest" in giving physicians a "broad choice" of medical devices).[5] Ultimately, denying surgeons access to the ENSEAL X1 would be contrary to the interests of patients, who benefit from having surgeons use the device they most prefer. *See, e.g.*, *Ethicon Endo-Surgery v. U.S. Surgical Corp.*, 855 F. Supp. 1500, 1517 (S.D. Ohio 1994).

The sole public interest cited by Covidien is the public interest in respecting the patent system. Dkt. No. 39 (Covidien Mem.) at 25. This interest is not enough to overcome the clear interest in protecting the public health, given the circumstances presented here. *See Cordis*, 99 F. App'x at 935 (The public's interest in upholding the exclusive rights of a patentee "cannot control in every case without obliterating the public interest component of the preliminary injunction inquiry."); *MercExchange*, 500 F. Supp. 2d at 586 ("[W]hile preserving the integrity of the patent system will always be a consideration of the public-interest analysis, it cannot be allowed to dominate such analysis lest a presumption results."). In light of the public's fundamental interest in having access to the best medical treatment, and the absence of any meaningful competing interest, Covidien's request for a preliminary injunction should be denied.

CONCLUSION

For all of these reasons, Covidien's request for a preliminary injunction should be denied.

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[5] *See also Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, No. CV-03-0597, 2009 U.S. Dist. LEXIS 31328, at *30 (D. Ariz. Mar. 31, 2009), *aff'd*, 670 F.3d 1171, *vacated in part on reconsideration*, 682 F.3d 1003 (Fed. Cir. 2012), *vacated in part on reh'g en banc*, 476 F. App'x 747 (Fed. Cir. 2012) (finding that the "strength of [the public interest] factor alone preclude[d the court] from imposing a permanent injunction" because it would remove from the market medical devices that surgeons use in performing lifesaving medical treatments—"[t]he risk is too great").

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Respectfully submitted,

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CERTIFICATE OF SERVICE

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